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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-------------|-----------------------|---------------------|------------------|
| 09/918,039 | 07/30/2001 | Yong Mi Choi-Sledeski | P24450-E US1 | 3370 |
| 7590 12/02/2004 | | | EXAMINER | |
| Synnestvedt & Lechner LLP 2600 Aramark Tower 1101 Market Street Philadelphia, PA 19107-2950 | | | TRUONG, TAMTHOM NGO | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 1624 | |
| DATE MAILED: 12/02/2004 | | | | |

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/918,039

Applicant(s)

CHOI-SLEDESKI ET AL.

Examiner

Tamthom N. Truong

Art Unit

1624

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 August 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1, 2, 6, 8-12, 14, 22 and 24-41 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1, 2, 6, 8-12, 14, 22, and 24-41 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Applicant's amendment of 8-20-04 has been considered. Due to the extensive number of rings or ring systems present, the following restriction is required. The previous 112, and 102 rejections are set aside right now, and will be addressed once an election is made.

Claims 3-5, 7, 13, 15-21, and 23 are cancelled.

Claims 1, 2, 6, 8-12, 14, 22, and 24-41 are pending.

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

1. Claims 1, 2, 6, 8-12, 14, 22, and 24-34, drawn to compounds of formula I,

wherein:

Ar¹ is pyrrolo[2,3-c]pyridinyl;

R₂ is SO₂-phenyl, or SO₂-naphthyl;

Pharmaceutical composition thereof, and method of treating thrombus formation (inhibiting Factor Xa) using said compounds;
classified in classes 514, 546, various subclasses depending on substituents.

2. Claims 1, 2, 6, 8-12, 14, 22, and 24-34, drawn to compounds of formula I

wherein:

Ar¹ is pyrrolo[2,3-c]pyridinyl;

R₂ is SO₂-(5-membered heteroaryl or heterocyclyl);

Pharmaceutical composition thereof, and method of treating thrombus formation (inhibiting Factor Xa) using said compounds; classified in classes 514, 546, various subclasses depending on substituents.

3. Claims 1, 2, 6, 8-12, 14, 22, and 24-34, drawn to compounds of formula I, wherein:

Ar^1 is pyrrolo[2,3-c]pyridinyl;

R_2 is SO_2 -(6-membered heteroaryl)

Pharmaceutical composition thereof, and method of treating thrombus formation (inhibiting Factor Xa) using said compounds; classified in classes 514, 546, various subclasses depending on substituents.

4. Claims 1, 2, 6, 8-12, 14, 22, and 24-34, drawn to compounds of formula I wherein:

Ar^1 is pyrrolo[2,3-c]pyridinyl;

R_2 is SO_2 -quinolinyl;

Pharmaceutical composition thereof, and method of treating thrombus formation (inhibiting Factor Xa) using said compounds; classified in classes 514, 546, various subclasses depending on substituents.

5. Claims 1, 2, 6, 8-12, 14, 22, and 24-34, drawn to compounds of formula I wherein:

Ar^1 is pyrrolo[2,3-c]pyridinyl;

R_2 is SO_2 -benzopyranyl;

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Pharmaceutical composition thereof, and method of treating thrombus formation (inhibiting Factor Xa) using said compounds; classified in classes 514, 546, various subclasses depending on substituents.

6. Claims 1, 2, 6, 8-12, 14, 22, and 24-34, drawn to compounds of formula I, wherein:

Ar¹ is pyrrolo[2,3-**b**]pyridinyl;

R₂ is SO₂-phenyl, or SO₂-naphthyl;

Pharmaceutical composition thereof, and method of treating thrombus formation (inhibiting Factor Xa) using said compounds; classified in classes 514, 546, various subclasses depending on substituents.

7. Claims 1, 2, 6, 8-12, 14, 22, and 24-34, drawn to compounds of formula I wherein:

Ar¹ is pyrrolo[2,3-**b**]pyridinyl;

R₂ is SO₂-(5-membered heteroaryl or heterocyclyl);

Pharmaceutical composition thereof, and method of treating thrombus formation (inhibiting Factor Xa) using said compounds; classified in classes 514, 546, various subclasses depending on substituents.

8. Claims 1, 2, 6, 8-12, 14, 22, and 24-34, drawn to compounds of formula I, wherein:

Ar¹ is pyrrolo[2,3-**b**]pyridinyl;

R₂ is SO₂-(6-membered heteroaryl)

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Pharmaceutical composition thereof, and method of treating thrombus formation
(inhibiting Factor Xa) using said compounds;

classified in classes 514, 546, various subclasses depending on substituents.

9. Claims 1, 2, 6, 8-12, 14, 22, and 24-34, drawn to compounds of formula I
wherein:

Ar¹ is pyrrolo[2,3-b]pyridinyl;

R₂ is SO₂-quinolinyl;

Pharmaceutical composition thereof, and method of treating thrombus formation
(inhibiting Factor Xa) using said compounds;

classified in classes 514, 546, various subclasses depending on substituents.

10. Claims 1, 2, 6, 8-12, 14, 22, and 24-34, drawn to compounds of formula I
wherein:

Ar¹ is pyrrolo[2,3-b]pyridinyl;

R₂ is SO₂-benzopyranyl;

Pharmaceutical composition thereof, and method of treating thrombus formation
(inhibiting Factor Xa) using said compounds;

classified in classes 514, 546, various subclasses depending on substituents.

11. Claims 1, 2, 6, 8-12, 14, 22, and 24-34, drawn to compounds of formula I,
wherein:

Ar¹ is pyrrolo[3,2-c]pyridinyl;

R₂ is SO₂-phenyl, or SO₂-naphthyl;

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Pharmaceutical composition thereof, and method of treating thrombus formation (inhibiting Factor Xa) using said compounds; classified in classes 514, 546, various subclasses depending on substituents.

12. Claims 1, 2, 6, 8-12, 14, 22, and 24-34, drawn to compounds of formula I wherein:

Ar¹ is pyrrolo[3,2-c]pyridinyl;

R₂ is SO₂-(5-membered heteroaryl or heterocyclyl);

Pharmaceutical composition thereof, and method of treating thrombus formation (inhibiting Factor Xa) using said compounds; classified in classes 514, 546, various subclasses depending on substituents.

13. Claims 1, 2, 6, 8-12, 14, 22, and 24-34, drawn to compounds of formula I, wherein:

Ar¹ is pyrrolo[3,2-c]pyridinyl;

R₂ is SO₂-(6-membered heteroaryl)

Pharmaceutical composition thereof, and method of treating thrombus formation (inhibiting Factor Xa) using said compounds; classified in classes 514, 546, various subclasses depending on substituents.

14. Claims 1, 2, 6, 8-12, 14, 22, and 24-34, drawn to compounds of formula I wherein:

Ar¹ is pyrrolo[3,2-c]pyridinyl;

R₂ is SO₂-quinolinyl;

Pharmaceutical composition thereof, and method of treating thrombus formation (inhibiting Factor Xa) using said compounds; classified in classes 514, 546, various subclasses depending on substituents.

15. Claims 1, 2, 6, 8-12, 14, 22, and 24-34, drawn to compounds of formula I wherein:

Ar¹ is pyrrolo[3,2-c]pyridinyl;

R₂ is SO₂-benzopyranyl;

Pharmaceutical composition thereof, and method of treating thrombus formation (inhibiting Factor Xa) using said compounds; classified in classes 514, 546, various subclasses depending on substituents.

16. Claims 1, 2, 6, 8-12, 14, 22, and 24-34, drawn to the remaining compounds of formula I wherein the combination of Ar¹ and R₂ is not in the above groups.

Pharmaceutical composition thereof, and method of treating thrombus formation (inhibiting Factor Xa) using said compounds; classified in classes 514, 546, various subclasses depending on substituents. Further restriction will be required if this group is elected.

17. Claims 35-41, drawn to the combination therapy and/or composition comprising additional agent(s); classified in class 514, various subclasses depending on the additional agents. Further restriction will be required if this group is elected.

The inventions are distinct, each from the other because of the following reasons:

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a. Inventions groups 1-17 are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the combinations of rings represented by Ar¹, R₂ and the pyrrolidinone ring define the different inventions.

b. Although all groups share the ring of *pyrrolidinone*, said ring alone does not sufficiently define the invention, and does not contribute to the art. Therefore, it is the combination of the *pyrrolidinone* with Ar¹ and R₂ that gives each group a distinct physical, chemical and/or biological properties, and thus sets apart the compounds of one group from those of the others. Thus, a reference that anticipated, or rendered obvious one group would not do so to the others, and so, a separate search is required for each group.

Because these inventions are distinct for the reasons given above and the search required for Group 1 is not required for Group 2-17, and the search for all 17 distinct invention would impose a serious burden upon the examiner in charge of this invention, restriction for examination purposes as indicated is proper.

Due to the complexity of the grouping, the restriction is presented in writing.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the

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application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

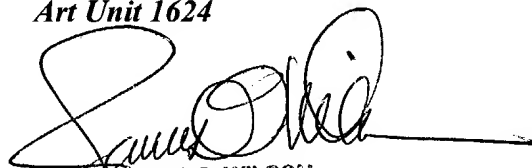
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Tamthom N. Truong whose telephone number is 571-272-0676. The examiner can normally be reached on M-F (10:00-6:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O Wilson can be reached on 571-272-0661. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Tamthom N. Truong
Examiner
Art Unit 1624

11-15-04


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